

**Appendix B**  
**Clean Copy of Pending Claims Without Markings**

18. The composition according to claim 21, wherein the rAAV further comprises a promoter.

19. The composition according to claim 21, wherein the rAAV further comprises a constitutive promoter.

20. The composition according to claim 19, wherein the promoter is selected from the group consisting of the cytomegalovirus immediate early promoter and the Rous sarcoma virus LTR promoter.

21. A composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier,

wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE), and (c) 3' AAV ITRs, and

wherein the level of contaminating adenoviral helper virus is no greater than that obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation, and wherein the ApoE is expressed in the absence of a cytotoxic immune response directed against recombinant AAV-transduced cells expressing the ApoE.

22. The composition according to claim 21, wherein said composition comprises at least  $10^9$  particles rAAV.

23. The composition according to claim 21, wherein the composition comprises  $2.5 \times 10^{10}$  to  $5 \times 10^{10}$  genomes of rAAV.

24. The composition according to claim 21, wherein the composition comprises  $5 \times 10^{10}$  to  $5 \times 10^{11}$  genomes of rAAV.

26. A method of delivering apolipoprotein E (apoE) to a patient in need of treatment of atherosclerosis, said method comprising the step of administering to the patient a composition comprising a recombinant adeno-associated virus (AAV) suspended in a biologically compatible carrier, wherein said recombinant AAV comprises (a) 5' AAV inverted terminal repeats (ITRs), (b) nucleic acid sequences encoding human apolipoprotein E (ApoE), and (c) 3' AAV ITRs, wherein the level of contaminating adenoviral helper virus is no greater than that obtained by subjecting said recombinant AAV to four rounds of cesium chloride gradient centrifugation, and wherein the ApoE in said composition is expressed in the patient in the absence of a cytotoxic immune response directed against recombinant AAV-transduced cells expressing the ApoE.

27. The method according to claim 26, wherein the apoE is administered intramuscularly.

28. The method according to claim 26, wherein said composition comprises at least  $10^9$  genomes rAAV.